COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.9.2008
C(2008)5597

NOT FOR PUBLICATION

COMMISSION DECISION

of 26.9.2008

amending the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4(5) thereof,

Having regard to the notifications submitted by Encysive (UK) Limited under Article 4(1) of Regulation (EC) No 1085/2003,

Whereas:

(1) The European Medicines Agency acknowledged, between 13 February 2008 and 13 August 2008, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.

(2) The marketing authorisation should be updated, and Decision C(2006)3721 of 10 August 2006 amended accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2006)3721 should therefore be replaced,

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1 OJ L 136, 30.4.2004, p. 1, Regulation as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

2 OJ L 159, 27.6.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2006)3721 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/679/IA/013	8.b.1 (IA) (EU/1/06/353/001-005)

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, 26.9.2008

For the Commission
Heinz ZOUREK
Director-General